

§ 460.10

operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

Subpart B—PACE Organization Application and Evaluation

§ 460.10 Purpose.

This subpart sets forth application requirements for an entity that seeks approval from HCFA as a PACE organization.

§ 460.12 Application requirements.

(a) *General.* (1) An individual authorized to act for the entity must submit to HCFA a complete application that describes how the entity meets all requirements in this part.

(2) HCFA evaluates only complete applications from entities located in States with approved State plan amendments electing PACE as an optional Medicaid benefit.

(3) HCFA accepts applications from entities that seek approval as PACE organizations beginning on February 22, 2000 except for the following:

(i) Beginning on November 24, 1999, HCFA accepts applications from entities that meet the requirements for priority consideration in processing of applications, as provided in § 460.14.

(ii) Beginning on January 10, 2000, HCFA accepts applications from entities that meet the requirements for special consideration in processing applications, as provided in § 460.16.

(b) *State assurance.* An entity's application must be accompanied by an assurance from the State administering agency of the State in which the program is located indicating that the State—

(1) Considers the entity to be qualified to be a PACE organization; and

(2) Is willing to enter into a PACE program agreement with the entity.

§ 460.14 Priority consideration.

Until August 5, 2000, HCFA gives priority consideration in processing applications for PACE organization status to an entity that meets either of the following criteria:

(a) Is operating under PACE demonstration waivers under one of the following authorities:

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(1) Section 603(c) of the Social Security Amendments of 1983, as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985.

(2) Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986.

(b) Has applied to operate under a PACE demonstration under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 as of May 1, 1997.

§ 460.16 Special consideration.

Until August 5, 2000, HCFA gives special consideration in processing applications to an entity that meets the following conditions:

(a) Indicated, by May 1, 1997, a specific intent to become a PACE organization through formal activities.

(b) Includes documentation of its formal activities.

§ 460.18 HCFA evaluation of applications.

HCFA evaluates an application for approval as a PACE organization on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained through on-site visits conducted by HCFA or the State administering agency.

(c) Information obtained by the State administering agency.

§ 460.20 Notice of HCFA determination.

(a) *Time limit for notification of determination.* Within 90 days after an entity submits a complete application to HCFA, HCFA takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

(3) Requests additional information needed to make a final determination.

(b) *Additional information requested.* If HCFA requests from an entity additional information needed to make a final determination, within 90 days after HCFA receives all requested information from the entity, HCFA takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

(c) *Deemed approval.* An application is deemed approved if HCFA fails to act on the application within 90 days after one of the following dates:

(1) The date the application is submitted by the organization.

(2) The date HCFA receives all requested additional information.

(d) *Date of submission.* For purposes of the 90-day time limit described in this section, the date that an application is submitted to HCFA is the date on which the application is delivered to the address designated by HCFA.

§ 460.22 Service area designation.

(a) An entity must state in its application the service area it proposes for its program.

(b) HCFA, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

§ 460.24 Limit on number of PACE program agreements.

(a) *Numerical limit.* Except as specified in paragraph (b) of this section, HCFA does not permit the number of PACE organizations with which agreements are in effect under this part or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, to exceed the following:

(1) As of August 5, 1997—40.

(2) As of each succeeding August 5, the numerical limit for the preceding year plus 20, without regard to the actual number of agreements in effect on a previous anniversary date. (For example, the limit is 60 on August 5, 1998 and 80 on August 5, 1999.)

(b) *Exception.* The numerical limit does not apply to a private, for-profit PACE organization that meets the following conditions:

(1) Is operating under a demonstration project waiver under section 1894(h) and 1934(h) of the Act.

(2) Was operating under a waiver and subsequently qualifies for PACE orga-

nization status in accordance with sections 1894(a)(3)(B)(ii) and 1934(a)(3)(B)(ii) of the Act.

Subpart C—PACE Program Agreement

§ 460.30 Program agreement requirement.

(a) A PACE organization must have an agreement with HCFA and the State administering agency for the operation of a PACE program by the PACE organization under Medicare and Medicaid.

(b) The agreement must be signed by an authorized official of the PACE organization.

§ 460.32 Content and terms of PACE program agreement.

(a) *Required content.* A PACE program agreement must include the following information:

(1) A designation of the service area of the organization's program. The area may be identified by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, as applicable. HCFA and the State administering agency must approve any change in the designated service area.

(2) The organization's commitment to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans With Disabilities Act.

(3) The effective date and term of the agreement.

(4) A description of the organizational structure of the PACE organization and information on administrative contacts, including the following:

(i) Name and phone number of the program director.

(ii) Name of all governing body members.

(iii) Name and phone number of a contact person for the governing body.

(5) A participant bill of rights approved by HCFA and an assurance that the rights and protections will be provided.

(6) A description of the process for handling participant grievances and appeals.